

**DECLARATION (37 CFR 1.63) FOR UTILITY OR DESIGN APPLICATION USING AN
APPLICATION DATA SHEET (37 CFR 1.76)**

Title of Invention Pulsatile Release Compositions of Milnacipran

As the below named inventor(s), I/we declare that:

This declaration is directed to:

- ☐ The attached application, or
☒ Application No. 10/690,872, filed on October 22, 2003,
☐ as amended on _____ (if applicable);

I/we believe that I/we am/are the original and first inventor(s) of the subject matter which is claimed and for which a patent is sought;

I/we have reviewed and understand the contents of the above-identified application, including the claims, as amended by any amendment specifically referred to above;

I/we acknowledge the duty to disclose to the United States Patent and Trademark Office all information known to me/us to be material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

All statements made herein of my/own knowledge are true, all statements made herein on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001, and may jeopardize the validity of the application or any patent issuing thereon.

FULL NAME OF INVENTOR(S)

Inventor one: Jane Hirsh

Signature: Jane Hirsh Citizen of: USA

Inventor two: Roman V. Rariy

Signature: Roman V. Rariy Citizen of: Russia

Inventor three: Michael Hefferman

Signature: Michael Hefferman Citizen of: USA

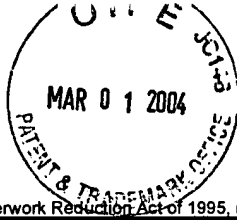
Inventor four: _____

Signature: _____ Citizen of: _____

☐ Additional inventors or a legal representative are being named on _____ additional form(s) attached hereto.

This collection of information is required by 35 U.S.C. 115 and 37 CFR 1.63. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1 minute to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PTO/SB/81 (06-03)

Approved for use through 11/30/2005. OMB 0651-0035

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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**POWER OF ATTORNEY
and
CORRESPONDENCE ADDRESS
INDICATION FORM**

Application Number	10/690,872
Filing Date	October 22, 2003
First Named Inventor	Jane Hirsh
Title	Pulsatile Release Compositions of Milnacipran
Art Unit	
Examiner Name	
Attorney Docket Number	CP 107P

I hereby appoint:

☒ Practitioners at Customer Number:**23579**

OR

☐ Practitioner(s) named below:

Name	Registration Number
Patrea L. Pabst	31,284
Rivka D. Monheit	48,731
Todd S. Hofmeister	53,029

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please recognize or change the correspondence address for the above-identified application to:

☒ The above-mentioned Customer Number:

OR

☐ The address associated with Customer Number:**23579**

OR

<input type="checkbox"/> Firm or Individual Name	Patrea L. Pabst; Holland & Knight LLP				
Address	Suite 2000, One Atlantic Center				
Address	1201 West Peachtree Street, N.E.				
City	Atlanta	State	GA	Zip	30309-3400
Country	USA				
Telephone	(404) 817-8473	Fax	(404) 817-8588		

I am the:

☐ Applicant/Inventor.☒ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)**SIGNATURE of Applicant or Assignee of Record**

Name	Jane Hirsh		
Signature	[Handwritten Signature]		
Date	2/17/2004	Telephone	1-404-726-4000

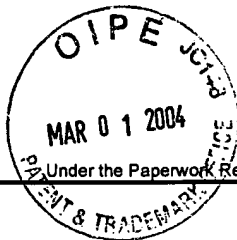
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 37 CFR 1.31 and 1.33. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 3 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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CP 107P - 085337/00012



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

STATEMENT UNDER 37 CFR 3.73(b)Applicant/Patent Owner: Jane Hirsh, Roman V. Rariy, and Michael HeffernanApplication No./Patent No.: 10/690,872 Filed/Issue Date: October 22, 2003Entitled: Pulsatile Release Compositions of MilnacipranCollegium Pharmaceutical, Inc., a corporation of the State of Delaware

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or2. ☐ an assignee of less than the entire right, title and interest.The extent (by percentage) of its ownership interest is _____ %
in the patent application/patent identified above by virtue of either:A. [☒] An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.**OR**

B. [] A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

1. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

3. From: _____ To: _____

The document was recorded in the United States Patent and Trademark Office at
Reel _____, Frame _____, or for which a copy thereof is attached.

[] Additional documents in the chain of title are listed on a supplemental sheet.

[] Copies of assignments or other documents in the chain of title are attached.

[NOTE: A separate copy (i.e., the original assignment document or a true copy of the original document) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.08]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

2/17/2004
Date1-401-762-2000
Telephone numberJane Hirsh
Typed or printed nameMrs. Jane C. Hirsh
Signature_____
Title

This collection of information is required by 37 CFR 3.73(b). The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

ASSIGNMENT

We, Jane Hirsh of 15 Peirce Road, Wellesley, Massachusetts 02581; Roman V. Rariy of 245 Kelton Street, Allston, Massachusetts 02134; and Michael Heffernan of 41 Garrison Road, Hingham, Massachusetts 02043, in consideration of ten dollars and other valuable consideration paid to us by Collegium Pharmaceutical, Inc., a corporation of the State of Delaware, having its principal place of business at 400 Highland Corporate Drive, Cumberland, Rhode Island 02864 (hereinafter "said Assignee"), the receipt of which is hereby acknowledged, do hereby sell, assign and transfer unto said Assignee, its successors and assigns, the entire interest for the United States of America, and its territories and all foreign countries and jurisdictions, including all rights of priority under the International Convention for the Protection of Industrial Property, in a certain invention or improvement in "*Pulsatile Release Compositions of Milnacipran*" described in U.S. Serial No. 10/690,872 filed in the United States Patent and Trademark Office on October 22, 2003, by Jane Hirsh, Roman V. Rariy, and Michael Heffernan, and in the provisional applications to which priority is claimed, being U.S. Provisional Application Serial Nos. 60/421,640 filed on October 25, 2002; 60/431,626 filed on December 5, 2002; 60/431,627 filed on December 5, 2002; 60/431,861 filed on December 9, 2002; 60/431,906 filed on December 9, 2002; 60/443,618 filed on January 29, 2003; 60/458,994 filed on March 28, 2003; 60/458,995 filed on March 28, 2003; and 60/459,061 filed on March 28, 2003, and in all Letters Patent of the United States and its territories and all foreign countries and jurisdictions which may or shall be granted on said invention, or any parts thereof, or on said application, or any provisional, divisional, continuation, continuation-in-part, reissue, or other applications based in whole or in part thereon. And we agree, for ourselves and our executors and administrators, with said Assignee and its successors and assigns, but at its or their expense or charges, hereafter to execute all applications, amended specifications, deeds or other instruments, and to do all acts necessary or proper to secure the grant of Letters Patent in the United States and its territories and in all other foreign countries and jurisdictions to said Assignee, with specifications and claims in such form as shall be approved by the counsel of said Assignee, and to vest and confirm in said Assignee, its successors and assigns, the legal title to all such patents.

Title: "Pulsatile Release Compositions of Milnacipran"
By: Jane Hirsh, Roman V. Rariy, and Michael Heffernan
Filed: October 22, 2003
ASSIGNMENT

And we do hereby authorize and request the Commissioner of Patents and Trademarks of the United States to issue such Letters Patent as shall be granted upon said application or applications based thereon to said Assignee, its successors and assigns.

WITNESS my hand and seal this 12th day of February, 2004.

Jane Hirsh
Jane Hirsh

State of Massachusetts
County of Plymouth

Then personally appeared the above named Jane Hirsh and acknowledged the foregoing instrument to be her free act and deed, before me this 12th day of February, 2004.

Nancy J. Gustafson
Notary Public

My Commission expires: My Commission Expires March 4, 2005

Title: "Pulsatile Release Compositions of Milnacipran"
By: Jane Hirsh, Roman V. Rariy, and Michael Heffernan
Filed: October 22, 2003
ASSIGNMENT

WITNESS my hand and seal this 12th day of February, ~~2003~~ ²⁰⁰⁴.

Roman V. Rariy
Roman V. Rariy

State of Massachusetts
County of Dorchester

Then personally appeared the above named Roman V. Rariy and acknowledged the foregoing instrument to be his free act and deed, before me this 12th day of February, ~~2003~~ ²⁰⁰⁴.

Nancy J. Gustafson
Notary Public

My Commission expires: My Commission Expires March 4, 2005

Title: "Pulsatile Release Compositions of Milnacipran"
By: Jane Hirsh, Roman V. Rariy, and Michael Heffernan
Filed: October 22, 2003
ASSIGNMENT

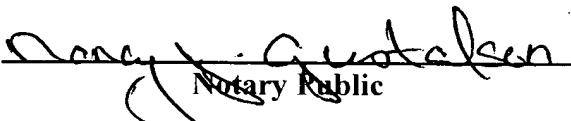
WITNESS my hand and seal this 22nd day of February, 2003.



Michael Heffernan

State of Massachusetts
County of Dorchester

Then personally appeared the above named Michael Heffernan and acknowledged the foregoing instrument to be his free act and deed, before me this 22th day of February, ~~2003~~ 2004



Notary Public

My Commission expires: My Commission Expires March 4, 2005

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